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degussa.

Degussa Corporation

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October 6, 2003

Document Processing Center EPA East (Mail Code 7407M) Attn: TSCA Section 8(e) U.S. Environmental Protection Agency 1201 Constitution Avenue, NW Washington, DC 20460-0001

Contain NO CBI



Dear Madam or Sir:

Enclosed are summaries of 43 toxicology studies conducted by or for Degussa AG in Germany. These summaries reflect the results of one or more studies conducted on each of 21 chemical substances. Twelve of the summaries include information which we are reporting pursuant to Section 8(e) of the Toxic Substances Control Act (TSCA). The remaining nine studies include information that suggests that the test substance may cause adverse health or environmental effects at high exposure levels. However, because these substances are manufactured or imported in the United States only in limited quantities for use as intermediates in chemical synthesis, they do not currently present a substantial risk to health or the environment. We are therefore submitting them to EPA on a "For Your Information" basis.

These 21 summaries are being submitted pursuant to a data review that Degussa is conducting in connection with its implementation of a new computer system that will permit Degussa Corporation in the United States to access data previously available only to Degussa AG in Germany. Recognizing that a large number of these studies might need to be reported under TSCA 8(e), Degussa proactively contacted EPA in mid 2002 and proposed to review the studies in batches and submit any 8(e) reportable data to EPA within 15 business days (now 30 calendar days) of completing its review of each batch. Degussa estimated that the review would take approximately six month to complete. In a memorandum received in November 2002, the Agency concurred in this approach.

These studies were made available to Degussa Corporation in April 2003. Degussa's toxiciologists in Germany have reviewed more than 750 studies on approximately 100 chemical substances and prepared English summaries of the results of 70 studies for evaluation by scientists in the United States for reporting under TSCA Section 8(e). This submission represents Degussa's review of this first batch of studies by our scientists in Germany and the United States, which was completed on September 12, 2003. Degussa has determined that approximately 1500 studies remain to be reviewed. As we have separately informed Ms. Ann Pontius of the Toxics and Pesticides Enforcement Division, we estimate that the review of the remaining studies will take an additional nine months to complete. We will continue to submit reportable and FYI studies to EPA as our review of subsequent batches is completed.

We appreciate your attention to this matter and request your comments regarding the approach we have taken. Please do not hesitate to call me at (973) 541-8047 if you have any questions or wish to discuss this matter further.

Best regards,

Shaun F. Clancy, Ph.D.

26929Th0929

Degussa Corporation

Memo

To:

File

From:

Shaun Clancy

CC:

Date:

10/06/03

Re:

TSCA 8(e) Review - 507-20-0

One endpoints were provided by Fine Chemicals for 507-20-0

Acute Oral Toxicity

This chemical is used as an intermediate in organic synthesis and is not expected to be used in a way such that human exposure outside of an industrial setting will occur or that an environmental exposure will result. Appropriate Personal Protective Equipment is specified in the MSDS as is warnings not to allow the substance to be released. When used correctly the risk for human and environmental exposure is minimal.

The results of the oral tox study indicate possible neurotoxic effects. However, given the high dose, other observed toxic effect, and the reversibility of the effects after the dosing period in the surviving animals make it unclear that the observed effects are indicators of neurotoxicity. The results will be reported under TSCA 8(e).

Contains No CRI

degussa.

Fax

To:

Shaun Clancy

DEGUSSA AG

S-SR-US-EHS

Fax-No. Recipient:

001-973 541 8040

Pages (total):

078

CC:

Dr. W. Mayr/FC-TME-CSM

Initial notice of Information for possible TSCA 8e submission tert-Butylchloride, CAS No. 507-20-0

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Dear Shaun,

please find attached data obtained for the above mentioned substance for assessment of possible TSCA reportability.

I am at your disposal for any further questions.

Please find attached an English translation of the report on acute oral toxicity.

Best regards

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Fine chemicals Chemicals Safety Management

FC-TME-CSM/Dr.Jbl/sch

July 14, 2003

1.4

S.02/08

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T-+49 6181 59-3900 F 149 6181 59-2083

Fine chemicals Chemicals Safety Management July 14, 2003

Dogussa AG

Germany

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Initial Notice of Information to be assessed for Possible TSCA, Sec. 8e Reporting

| Name / Trade name of the Substance | Tert-Butylchloride | |
|------------------------------------|--------------------|--|
| CAS-No.: | 507-20-0 | |
| Human Health Effects | x | |
| Environmental Effects | | |
| Degussa-Study-No.: | 80-0080-DKT | |
| Other Source of information: | | |

Summary of Adverse Effects:

Human health: Acute oral toxicity study in rats Source, Degussa AG, unpublished report No. 80-0080-DKT Guideline: not stated, non-GLP.

5 male, 5 female animals per group. Dose levels tested were 2.5, 3.2, 4.0, 5.0 ml/kg bw.

The LD50 was determined to be 3.5 ml/kg bw corresponding to 2951 mg/kg bw using a density of 0.843 g/ml. The following clinical signs were reported that might be indicative of neurotoxicity: Spasms in one animal of the low dose group, coordination disturbance in 2 male and 2 female animals of the low dose group, 5 male and 3 female animals of the 3.2 ml/kg dose group and one female of the 4.0 ml/kg dose group. Increased respiratory frequency in one male animal of the 2.5 and 4.0 ml/kg dose groups. Reduced motility in all male and 3 females of the low dose group and one male and one female of the 4.0 ml/kg dose group. Hunched posture of 2 females of the low dose group and most of the animals at 3,2 ml/kg as well as one male and one female animal at 4,0 ml/kg bw.

In the animals that died during the study hyperemia of the liver and the glandular stomach mucosa was observed. No macroscopic findings were observed in the animals that were sacrificed at the end of the study.

| Information by | Date: |
|-------------------|---------------|
| Dr. Sylvia Jacobi | July 14, 2003 |

Reprotox

Reproduktionstoxikologische Auftragsforschung GmbH

Vorbergweg 41 4400 Münster Phone: (02 51) 212234

HRC Huntingdon Research Centre Germany

October 20, 1980 No. __1793

REPROTOX Job No. 581/S
Acute Toxicity of tert. Butyl Chloride
in Male and Female Rats Following
Oral Administration

Degussa-Hüls AG – REG No.

80 0080

DKT

Customer:

Chemische Werke Huls AG Postfach 13 20 4370 Marl

Tert.-Butylchlorid_e.doc

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SUMMARY

According to these results, the acute oral LD₅₀ of "tert. butyl chloride" in rats 3.5 mL/kg body weight

95% confidence limits: 3.2-3.9 mL/kg body weight

-2-

-2-

RESPONSIBILITIES

Customer:

Chemische Werke Hüls AG, Postfach 13 20,

4370 Marl 1

Study director:

Dr. W. Worstmann

Test conducted by:

B.N. Charnley, M.L. Meisel

TEST SUBSTANCE

Substance name:

tert. butyl chloride

Chemical name:

2-chloro-2-methyl propane

Appearance:

clear liquid

Storage:

at 20°C in daylight

Shelf life:

no data

TEST ANIMALS AND HOUSING CONDITIONS

Species:

rat, strain: Sprague-Dawley, SPF

Breeder:

W. Gassner, Sulzfeld

Number of animals per dose and sex:

5 M and 5 F

Number of animals per cage:

5

Starting weight:

M 100-140 g; F 95-125 g

Conventional housing in air-conditioned room, room temperature 22°C ± 1°C,

Lighting: 12 hr rhythm (bright from 6:00 to 18:00 o'clock).

Feed: Ssniff R 10 (pollets) ad libitum, feed withdrawn ca. 16 hr before trial; feed offered again ca. 4 hr post applicationem.

Drinking water ad libitum.

Period of Study: September 1980

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TRIAL ARRANGEMENT / DOSAGE

| Group | Dose (mL/kg body weight) |
|-------------|---|
| I = control | 5.0 mL/kg body weight (distilled water) |
| П | 2.5 |
| Ш | 3.2 |
| <u>IV</u> | 4.0 |
| V | 5.0 |

PROCEDURE

The above-listed amounts of substance were administered once orally by gavage. The clinical signs were recorded several times on the day of administration, then daily.

Observation Time: 14 days

EVALUATION

Calculation of the LD₅₀ based on number of deaths (x/n) within 14 days after administration according to WEIL, C.S. (Biometrics, 8, 249, 1952).

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RESULTS

l) Lethality (x/n)

| Group Time | I = Control | II | III | IV | v |
|-----------------|----------------|------------|------------|------------|------------|
| up to 6 hr | M 0/5 F 0/5 | 0/5 | 0/5 | 1/5 | 0/5 |
| 6–24 hr | M 0/5 | 0/5 | 0/5 | 2/5 0/5 | 0/5 5/5 |
| 24-48 hr | F 0/5 M 0/5 | 0/5 0/5 | 0/5 1/5 | 0/5 2/5 | 5/5 0/5 |
| 3-7 days | F 0/5 M 0/5 | 0/5 0/5 | 2/5 0/5 | 2/5 0/5 | 0/5 0/5 |
| 7-14 days | F 0/5 M 0/5 | 0/5 0/5 | 0/5 0/5 | 0/5 | 0/5 |
| Total number | F 0/5 M 0/5 | 0/5 | 0/5 | 0/5 0/5 | 0/5 0/5 |
| of dead animals | F 0/5 | 0/5 0/5 | 1/5 2/5 | 3/5 4/5 | 5/5 5/5 |

2) Body Weight Development (g. mean values)

| Group | I - Control | П | III | T 77. | γ |
|----------------------------------|-------------|-----|-------|-------|-------|
| Day | | | 1111 | IV | V |
| Day of | M 111 | 113 | 128 | 110 | 107 |
| administration | F 108 | 112 | 113 | 106 | 103 |
| 7 th day of the study | M 171 | 166 | 184 | 163 | - 110 |
| 15th day of the | F 148 | 147 | 147 | 140 | |
| study | M 206 | 205 | 240 | 200 | |
| Study | F 162 | 164 | 173.3 | 155 | _ |

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3) Clinical signs

Following administration, most of the treated animals had ruffled fur and prone positions. Further, the following were observed:

- Spasms in one male animal after 2.5 mL/kg body weight.

- Coordination disorders in one male and two female animals of Group II (2.5 mL/kg body weight); in all male and three female rats of Group III (3.2 mL/kg body weight) and one female animal of Group IV (4.0 mL/kg body weight).
- Elevated respiration rate in one male animal after 2.5 mL/kg body weight and one male animal after 4.0 mL/kg body weight.
- Reduced motility in all male and three female rats of Group II (2.5 mL/kg body weight) and one male and one female animal of Group IV (4.0 mL/kg body weight).
- Pale extremities in one female animal after 2.5 mL/kg body weight and one male and one female animal after 4.0 mL/kg body weight.
- Hunched posture in two female rats after 2.5 mL/kg body weight; in the majority of animals after 3.2 mL/kg body weight and one male and one female animal after 4.0 mL/kg body weight.

After one week, the surviving animals were unremarkable.

The dead test animals had died within 1-3 days after administration of the substance. The body weight trends of the animals of both sexes corresponded essentially to those of the control animals.

Severe hyperemia of the liver and moderate hyperemia of the pancreatic mucosa was observed in the animals that died in the meantime. No remarkable pathological/anatomical findings were observed at dissection in the animals killed at the end of the study.

Münster, 10/17/1980

[Signature]
W. Worstmann, Doctor of Veterinary Medicine
Veterinary Specialist in Pharmacology and Toxicology

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